K063638

ST. JUDE MEDICAL

510(k) Summary

MAY 11 2007

Applicant Information

Submitted by: St. Jude Medical
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Maple Grove, MN 55311

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Date Prepared: 06 December, 2006

Device Information

Trade Name:	Proxis Flow Control System
Common Name:	Percutaneous Catheter
Classification Name:	Catheter, Percutaneous
Classification:	Class II per 21 CFR 870.1250
Product Code:	DQY

Device Description

The Proxis System has five major components: the Evacuation Sheath Catheter, Inflation System, Infusion Catheter, Lip Seal, and an Aspiration syringe.

The Evacuation Sheath Catheter has one proximal low-pressure compliant sealing balloon that is inflated to occlude the arterial vessel. A radiopaque marker at the balloon site facilitates visualization and intravascular placement of the catheter prior to inflation. The Evacuation Sheath has a sufficiently large inner diameter to accommodate standard therapeutic devices within its size range. The balloon is inflated using the Inflation System.

Devices can be deployed through the Evacuation sheath to the target site before, during or after the sealing balloon is inflated to occlude the vessel. Infusing ~0.5cc of contrast dye through the evacuation sheath catheter will produce a continuous "roadmap" of the lesion as an aid for the physician in guiding the therapeutic device to the lesion site.

Alternatively, while the vessel is occluded, therapeutic solutions like anticoagulant, cardioplegia and thrombolytics may be infused through the evacuation sheath catheter and stagnated in the target vessel/lesion during the delivery of the therapeutic device or after the deployment of the therapeutic device.

The Aspiration syringe is provided for the removal of stagnated fluid during aspiration. The infusion catheter may be used to infuse saline to augment the retrograde flow of fluid and the removal of stagnated fluid.

Intended Use

The Proxis Flow Control System controls the flow of fluids in the coronary and peripheral vasculature. This is achieved by temporary vessel occlusion to hold a column of fluid in the vessel stagnant. The stagnant column can be used to aid in the visualization of the lesion or be used as a means of local and temporary delivery of therapeutic solution(s). The safety and efficacy of this device as an embolic protection system has not been established. The Proxis Flow Control System is not indicated for use for embolic protection.

Predicate Device Comparison / Technological Characteristics

The Proxis Flow Control System, a modification of the current over-the-wire Proxis System (*K060651*), was created by decreasing the diameter of the catheter and sealing balloon. The Proxis Flow Control System device covered by this submission is identical in function, mechanism of action and intended use as the market cleared rapid-exchange Proxis System (*K042117*). In addition, the technological characteristics and ability to control fluid flow are identical to the over-the-wire Proxis System (*K060651*). Although the device may be similar in design to the device cleared under K060651, the Proxis Flow Control System is not intended for embolic protection.

Test Summary

The Proxis Flow Control System passed all verification specification criteria for dimensional, strength, functional, packaging, sterilization, biocompatibility, and shelf life tests. Test results confirm the device performs as intended without raising additional questions of safety and efficacy. Given the scope of the modifications incorporated to create the Proxis Flow Control System no additional animal or clinical data was deemed necessary.

Substantial Equivalence

The Proxis Flow Control System has the same indications for use, technical characteristics and principles of operation as the market cleared rapid exchange Proxis System (*K042117*). In addition, the Proxis Flow Control System has the same technological characteristics and flow control indication as the over-the-wire Proxis System (*K060651*). Although the device may be similar in design to the device cleared under K060651, the Proxis Flow Control System is not intended for embolic protection. The differences between this device and its predicate devices do not raise new questions of safety or efficacy. Therefore, the Proxis Flow Control System is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 11 2007

St. Jude Medical
c/o Ms. Shannon Springer
Sr. Regulatory Affairs Specialist
6550 Wedgewood Rd. N.
Maple Grove, MN 55311

Re: K063638
Proxis Flow Control System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: II (two)
Product Code: DQY
Dated: April 26, 2007
Received: April 27, 2007

Dear Ms. Springer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Vochmes

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K063638

Device Name: Proxis Flow Control System

Indications for Use:

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Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Bachman

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K063638